# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## the effect of educational program based on Newman's systemic model on the anxiety of eye surgery candidates

## Protocol summary

**Study aim**
the effect of educational program based on Newman's systemic model on the anxiety of eye surgery candidates

**Design**
Clinical trial with control group, with parallel groups, randomized, on 70 patients. Blocking will be used for randomization.

**Settings and conduct**
After obtaining the necessary permits, the researchers will introduce themselves to the officials of Valiasr hospital (AS) in Zanjan. After explaining the objectives of the study to the participants, they will be assured about the confidentiality of the information and the right to withdraw from the study. Patients are assigned to intervention and control groups by block method.

**Participants/Inclusion and exclusion criteria**
- Not having psychological diseases according to patients and companions - Age between 18 and 65 years - Having consent to study - Not taking anti-anxiety drugs - Not being addicted to opioids or narcotic painkillers - Having surgery in the eye area

**Intervention groups**
The study will have intervention and control groups. The control group will receive routine ward care. For the intervention group, an educational action based on Betty Newman's systemic nursing model will be carried out. Interventions will be carried out in three levels of primary, secondary and tertiary prevention.

**Main outcome variables**
The patients' anxiety will be measured before and after the intervention with the standard Spielberger questionnaire

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20230330057785N1**
Registration date: **2023-04-18, 1402/01/29**
Registration timing: **prospective**

Last update: **2023-04-18, 1402/01/29**
Update count: **0**

**Registration date**
2023-04-18, 1402/01/29

**Registrant information**

**Name**
ali aghajanloo

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-05-20, 1402/02/30

**Expected recruitment end date**
2023-12-21, 1402/09/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
the effect of educational program based on Newman's systemic model on the anxiety of eye surgery candidates

**Public title**
The effect of educational program on patients' anxiety

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Not having psychological diseases Not taking anti-anxiety drugs Not being addicted to opioids or narcotic painkillers Having consent to study Having surgery in the eye area

**Exclusion criteria:**

Lack of cooperation or patient satisfaction at any stage of the study Aggravation of the patient's conditions during the study and the need for advanced interventions

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The participants will be randomly divided into two intervention groups or control groups using the block method. For this purpose, with the help of the site www.sealedenvelope.com and by specifying the number of participants, the number of groups, the size of the blocks, the list and the order of the participants will be determined. Then the group list (intervention, control) of the participants will be written in the sealed envelope in order, and after determining the criteria for entering the patients, it will be opened to determine their group. It is necessary to explain that blocking will be done by someone other than the researcher.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Zanjan University of Medical Sciences

**Street address**

Zanjan University of Medical Sciences , Dr.Sobouti Blvd.

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**Postal code**

4513956184

**Approval date**

2023-03-12, 1401/12/21

**Ethics committee reference number**

IR.ZUMS.REC.1401.378

## Health conditions studied

### 1

**Description of health condition studied**

Candidate patients for eye surgery

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

anxiety

**Timepoint**

Before and after the intervention

**Method of measurement**

Spielberger questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group:Intervention group: The day before the surgery, the intervention will be performed by the researcher according to Betty Newman's systemic nursing model. The examination tool provided by Betty Newman in this model is related to the totality of the individual and includes the following 3 principles: 1- Full knowledge of the factors that affect the understanding of the patient. 2- Approving and valuing a stressor by the patient and caregiver. 3- Factors that affect the caregiver's mind in examining the patient's condition, In this regard, the researcher identifies the factors affecting their anxiety. In the evaluation stage of Newman's systemic model, first, potential/actual tensions, appropriate goals and strategies for actions will be determined, and then natural and flexible defense lines will be strengthened, in which the penetration of stressful factors into the line will be strengthened. Natural defenses will be prevented and the intensity of the reaction will be reduced. The educational content at the level of first prevention includes: explaining the eye anatomy, the role of proper nutrition in relieving stress and anxiety and creating confidence in the hospital and operating room environment, post-operative care and

instructions (how to bathe, the position of the patient while sleeping, and taking medications) Was.In the second level of prevention, the compromised natural and flexible defense lines will be restored. The intervention aimed at strengthening the internal defense lines will be carried out in order to reduce the reaction to stressful factors. Educational content at the level of secondary prevention includes: intervention based on the needs and stress factors diagnosed by the patient and the nurse based on Newman's stress factors:• Intrapersonal (awareness of rehabilitation stage, care at home, awareness of surgery, time to return to the ward, awareness of nutrition therapy)• Interpersonal (explaining hospital treatment methods, psychological support, communicating with patients and providing information about drugs)• It will be extroverted (providing information about insurance and paying expenses, talking to the health department and referring patients to charities, creating a calm environment and reducing noise).In the third level of prevention, the use of public system resources, including internal and external environments, will be maximized. The educational content in the third level of prevention will include: the implementation of Benson's sedation method to improve sedation responses.

**Category**
Rehabilitation

**2**

**Description**
The control group will receive routine ward care

**Category**
Rehabilitation

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Educational & Treatment Center of valiasr

**Full name of responsible person**
Ali Aghajanloo

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Valiasr hospital, Valiasr square, Zanjan

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Zanjan University of Medical Sciences

**Full name of responsible person**
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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Zanjan University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Zanjan University of Medical Sciences

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**Position**
Assistant Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available